UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA AND STATE OF NEW YORK, *ex rel.* EDWARD LACEY, *Plaintiffs,* v. VISITING NURSE SERVICE OF NEW YORK, *Defendant.*	Civil Action No. 14-CV-5739-AJN

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT VISITING NURSE SERVICE OF NEW YORK'S MOTION TO DISMISS
THE AMENDED COMPLAINT PURSUANT TO RULES 12(b)(6) AND 9(b)

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INTRODUCTION

Relator Edward Lacey is a former employee of Visiting Nurse Service of New York ("VNSNY"), a not-for-profit home health care agency founded in 1893. Lacey asserts in his Amended Complaint that VNSNY violated the federal False Claims Act ("FCA") and New York state analogue, by allegedly failing to comply with Medicare and Medicaid rules pertaining to physician-ordered Plans of Care for home health care services, as well as certain other regulations that govern how home health aide visits are to be supervised and billed. Lacey also alleges that VNSNY employees created false or inaccurate records of skilled nursing and therapy visits, but this theory is based solely upon the purported failure of field nurses to adhere to internal VNSNY visit verification policies and thus entirely fails to plead any cognizable violation of law.

While the Amended Complaint tries to paint a troubling picture, Lacey does so only by misconstruing the Medicare and Medicaid regulations governing payment for the types of services VNSNY provides. Lacey's allegations are premised on the unarticulated—and entirely erroneous—assumption that the government pays for such services on a per-hour or per-visit basis, in accordance with a fee-for-service payment methodology that both Medicare and the New York State Medicaid program have long since replaced. Built on this pervasive misconception, the Amended Complaint unsurprisingly does not—because Lacey cannot—identify even a single particular false claim that VNSNY submitted to any government health care program at the state or federal level. It is long-established that the FCA can be used only to pursue false claims for *payment* from the government. Because Lacey has failed to state a claim under the FCA—much less state one with the particularity required by Fed. R. Civ. P. 9(b)—the Court should dismiss the Amended Complaint with prejudice.

FACTUAL AND PROCEDURAL BACKGROUND

On July 28, 2014, Lacey commenced this action by filing a sealed FCA complaint on behalf of the United States and the State of New York. After conducting a lengthy investigation, the United States and New York both declined to intervene. ECF Dkts. 13, 14. On August 31, 2016, the Court ordered Lacey's complaint unsealed and served on VNSNY. ECF Dkt. 11. The First Amended Complaint ("Am. Compl.") was unsealed on September 9, 2016. ECF. Dkt. 16.

I. Medicare and Medicaid

Relator's Amended Complaint argues that VNSNY knowingly submitted false claims for payment for home health services that it billed to Medicare and to the New York State Medicaid program.[1] Home health services covered by Medicare and Medicaid include skilled nursing care, rehabilitation therapy, home health aide services, and some social services. Am. Compl. ¶ 17. The government does not reimburse home health agencies—including VNSNY—for any of these services on a per-hour, per-visit, or other fee-for-service basis. Instead, the government pays an acuity-adjusted fixed payment rate for whatever care is provided in a 60-day period, known as an "Episode of Care." 42 C.F.R. § 484.205(a); 10 N.Y.C.R.R. § 86-1.44. Critically, the entire package of home health services within each episode is reimbursed at "a predetermined rate." 42 C.F.R. § 484.205(a). That episodic reimbursement "represents payment in full for all costs associated with furnishing home health services" during the episode. *Id.* § 484.205(b).

The initiation of a reimbursable episode of care begins with a referral from a physician to a home health agency. The physician must certify that (1) home health services are required because the patient is or was confined to his or her home and needs intermittent skilled nursing

[1] Although the Amended Complaint alleges that VNSNY submitted false claims to both Medicare and Medicaid, Lacey's allegations chiefly (indeed, nearly exclusively) concern Medicare's requirements, which the Amended Complaint alleges are incorporated into Medicaid's rules. *See* Am. Comp. ¶ 26 ("All claims submitted to Medicaid for reimbursement must comply with all applicable Medicare requirements"). Lacey's Medicaid claims fail for the same reason his Medicare claims fail, as discussed below.

care, physical or speech therapy, or occupational therapy; (2) a Plan of Care "for furnishing such services to such individual has been established and is periodically reviewed by a physician"; and (3) the home health services are furnished while the patient is under the care of a physician. 42 U.S.C. § 1395f(a)(2)(C).

The home health agency then conducts an assessment of the patient and completes a form known as the Outcome Assessment Information Set ("OASIS"). Am. Compl. ¶ 20. The OASIS is used by Medicare to make a preliminary determination of the amount of reimbursement to be paid for an Episode of Care. The analysis takes into account the patient's acuity, reflecting his or her clinical and functional severity, the patient's primary diagnosis and co-morbidities, and the type and frequency of *therapy* visits (if any) that are projected.[2] *See* Centers for Medicare & Medicaid Services, Medicare Claims Processing Manual, Chapter 10 – Home Health Agency Billing ("Medicare Manual"), § 10.1.7, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c10.pdf; *see also* Am. Compl. ¶ 20. A payment amount for the Episode of Care is then determined based on the assignment of one of 153 "home health resources groups," or HHRGs, which represent tiers of care. Medicare Manual, §§ 10.1.7-10.1.8, 10.1.19.1 (payment is adjusted "based on whether one of three therapy thresholds (6, 14 or 20 visits) is met"). Importantly, the "number of therapy visits projected at the start of the episode, entered in OASIS" may vary from the number actually provided during the episode. Medicare Manual, § 10.1.7. The actual number is "confirmed by the visit information submitted on the claim" by the home health agency "at the end of the episode." *Id.*

Medicare pays for home health services in two stages: a partial prospective payment based upon the assignment of a preliminary HHRG and a final payment. The initial payment is

[2] To be clear, the frequency of nursing and home health aide visits (if any) are *not* projected as part of this analysis.

made in response to a Request for Anticipated Payment ("RAP"), and represents roughly half of the projected rate for the Episode of Care.[3] 42 C.F.R. § 484.205(b)(1)-(2). The remainder is paid after the Episode of Care ends, when the provider submits a final claim. *Id.*

The amount Medicare pays in response to a final claim may vary from what was forecasted at the beginning of the episode. First, as discussed above, Medicare rules make clear that the "number of therapy visits projected on the OASIS assessment at the start of the episode . . . will be confirmed by the visit information submitted in the line-item detail on the claim for the episode." Medicare Manual, § 10.1.19.1. In other words, because Medicare reconciles the final claim based upon the number of *therapy* visits in fact provided, and the number of therapy visits (though *not* the number of nursing or home health aide visits) factors into the determination of a HHRG score, the final claim could end in a different acuity-adjusted payment than originally forecasted. *See id.* Second, if "minimal services" were provided during the 60-day period, the final payment may be adjusted downward. A Low Utilization Payment Adjustment ("LUPA") is applied if four visits or fewer—aggregating the number of all therapy, nurse, and home health aide visits—were provided in a single episode. 42 C.F.R. § 484.205(c); Medicare Manual, § 10.1.17.[4] The Plan of Care prepared at the outset, in other words, has no role in Medicare's calculation or reconciliation of the final payment.

[3] Specifically, the initial payment is 60% for a given patient's first Episode of Care, and 50% for subsequent episodes that are part of the same sequence. 42 C.F.R. § 484.205(b)(1)-(2).

[4] The final payment may be adjusted upward by way of an "Outlier Payment" in some circumstances, *see* 42 C.F.R. § 484.205(e), but those circumstances are not at issue here. Medicare rules also provide for "Partial Episode Payment Adjustments" if a beneficiary "elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 60-day episode," triggering a new OASIS. 42 C.F.R. § 484.205(d) (emphasis added).

II. Lacey's Allegations

Lacey's first and principal contention is that VNSNY submitted false claims to the government by purportedly billing for home health services without furnishing all the visits or services listed in certain patients' Plans of Care. *See* Am. Compl. ¶ 27. Lacey asserts that "[p]roviding all the visits and services in the Plan of Care is . . . a prerequisite for government payment." Am. Compl. ¶ 50. This legal conclusion—entitled to no deference at the motion to dismiss stage—is simply incorrect; no statute or regulation sets forth such a requirement.

Lacey next contends that VNSNY nurses failed to adhere to VNSNY's internal documentation policies for verifying home visits through the agency's electronic patient signature and telephone confirmation systems. Am. Compl. ¶ 64. If anything, this theory is even more hollow and legally groundless than his first. Lacey does not identify any violation of Medicare rules in this respect, for there are no such rules. Instead, from this alleged non-compliance with internal verification mechanisms, Lacey draws the heroic inference that the underlying visits did not occur, or were meaningless charades. *See* Am. Compl. ¶ 71 (VNSNY "has known or should have known that all these visits did not occur or did not last long enough for VNSNY to provide any kind of meaningful care").

Finally, the Amended Complaint concludes with perfunctory assertions that VNSNY submitted false claims because it purportedly failed to comply with regulations that govern coverage of certain types of home health aide services, Am. Comp. ¶¶ 75-81; billing for low-income Medicare recipients who are "dually eligible" for Medicare and Medicaid, Am. Comp. ¶¶ 82-88; and nurse supervision of home health aides, Am. Compl. ¶¶ 89-91. Here, too, Lacey paints an incomplete and misleading picture that distorts or ignores the controlling regulations and rests on the patently false premise that these home health aide services are paid by the government per hour or on an analogous fee-for-service basis.

LEGAL STANDARDS

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). A complaint's factual content must allow the court to draw a reasonable inference that the defendant is liable for the misconduct alleged, establishing more than "a sheer possibility that a defendant has acted unlawfully." *Id.*; *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (emphasizing that courts do not accept conclusory allegations as true). Conclusory allegations and legal conclusions masquerading as facts will not suffice to defeat a motion to dismiss. *Achtman v. Kirby, McInerney & Squire, LLP*, 464 F.3d 328, 337 (2d Cir. 2006).

Lacey alleges violations of the federal FCA, 31 U.S.C. § 3729, and analogous provisions of the New York false claims act ("NYFCA"). "Because the NYFCA mirrors the FCA in many respects, it is appropriate to look toward federal law when interpreting the New York act." *United States v. N. Adult Daily Health Care Ctr.*, No. 13-CV-4933, 2016 WL 4703653, at *3 (E.D.N.Y. Sept. 7, 2016) (internal quotation marks omitted) (quoting *State ex rel. Seiden v. Utica First Ins. Co.*, 943 N.Y.S.2d 36, 39 (App. Div. 2012)); *Kane ex rel. United States v. Healthfirst, Inc.*, 120 F. Supp. 3d 370, 381 (S.D.N.Y. 2015) ("When interpreting the NYFCA, New York courts rely on federal FCA precedent.").

The FCA provisions at issue here impose punitive civil penalties, including treble damages and mandatory fines, on defendants who knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval; or, alternatively, knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. §§ 3729(a)(1)(A)-(B). Thus, to withstand a motion to dismiss, the Amended

Complaint must adequately allege that VNSNY "(1) made a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." *Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 43 (2d Cir. 2016).

ARGUMENT

The Court should dismiss the Amended Complaint because Lacey fails to plead the necessary element of falsity as to each FCA count. In addition, the Court should dismiss the Amended Complaint for the independent reason that, as described in Part II, *infra*, Lacey does not "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

I. RELATOR FAILS TO STATE AN FCA CLAIM UNDER RULE 12(B)(6) BECAUSE THE AMENDED COMPLAINT DOES NOT ADEQUATELY ALLEGE THAT ANY MEDICARE OR MEDICAID CLAIMS WERE FALSE, MUCH LESS MATERIALLY FALSE

To survive a motion to dismiss in an FCA action, Lacey must plead facts that demonstrate that claims for governmental payment that VNSNY submitted (or caused to be submitted) were actually *false* as a matter of law. Lacey fails to meet this burden, because the facts alleged in the Amended Complaint do not give rise to a claim for payment that is false under any legally cognizable theory.

a. Lacey's Allegations Concerning Deviations from Plans of Care Fail as a Matter of Law

The Amended Complaint's first allegation is that VNSNY submitted false claims for payment to the government because VNSNY did not provide home health services to some patients in lockstep with those patients' Plans of Care, and that VNSNY's alleged failure to do so violated government preconditions to payment. Am. Compl. ¶ 50 ("Providing all the visits and services in the Plan of Care is . . . a prerequisite for government payment."). This theory is fundamentally erroneous, as no law or regulation mandates as a condition of government reimbursement that a home health agency provide every service contemplated by a Plan of Care.

Despite pleading examples where VNSNY allegedly provided fewer services than a Plan of Care anticipated, *see* Am. Compl. ¶¶ 33-45, these allegations do not support an FCA claim because Lacey has not pled any claims for payment submitted to a government health care program (or any false record or statement that VNSNY used to get such a claim paid) that were actually false.

Lacey's contention appears to be that VNSNY's alleged deviations from Plans of Care rendered any subsequent claims for payment ineligible for any reimbursement whatsoever. *See* Am. Compl. ¶ 50. In other words, the Amended Complaint does not allege that VNSNY benefited from "excess" payments by billing for a greater number of services than the agency was authorized to provide within a given Episode of Care.[5] Instead, Lacey's contention is that VNSNY was entitled to no government reimbursement whatsoever for the episodes identified in the Amended Complaint. This is a theory of implied false certification—*i.e.*, that claims VNSNY submitted to the government were "false" by virtue of the agency's violation of material regulatory requirements for payment concerning Plans of Care with which VNSNY *implicitly* represented it had complied when submitting the claim to the government.[6]

The United States Supreme Court recently clarified that an implied false certification theory may lie where two conditions are met: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Universal Health Servs., Inc.*

[5] To make out such a claim, Lacey would have to allege facts plausibly showing that the final reconciled claim for payment at the end of an episode did not account fully for any deviations from the level of services forecasted at the outset of that episode. As discussed below, Lacey entirely fails to do so. *See* Part II, *infra*.

[6] The Second Circuit recognizes three bases of falsity under the FCA: (1) factual falsity, where a claim is made seeking payment for services never actually provided or for which the description of the goods or services is facially incorrect; (2) express false certification, where a claim for payment expressly and falsely certifies compliance with legal prerequisites to payment; and (3) implied false certification. *New York ex rel. Khurana v. Spherion Corp.*, No. 15-cv-6605, 2016 WL 6652735, at *14 (S.D.N.Y. Nov. 10, 2016) (citing *Mikes v. Straus*, 274 F.3d 687, 696-700 (2d Cir. 2001) and *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016)).

v. United States ex rel. Escobar, 136 S. Ct. 1989, 2001 (2016) ("*Escobar*"). The Amended Complaint does not come close to meeting this standard. As a threshold matter, Lacey does not allege any "specific representations" that VNSNY made to the government in connection with any claim. Indeed, the Amended Complaint does not even allege what the *claims* are to which Lacey's allegations relate, or at what point in Medicare's multi-step billing process VNSNY allegedly submitted such claims, much less any "specific representations." This is a fatal deficiency in Lacey's Plan of Care theory.

In addition, the *Escobar* framework requires that Lacey show that the regulatory non-compliance alleged was material to the government's payment decision; "mere non-compliance with a regulation is not enough to give rise to FCA liability." *United States ex rel. Scharff v. Camelot Counseling*, No. 13-CV-3791, 2016 WL 5416494 at *8 (S.D.N.Y. Sept. 28, 2016); *Escobar*, 136 S. Ct. at 2002 ("[B]illing parties are often subject to thousands of complex statutory and regulatory provisions. Facing [FCA] liability for violating any of them would hardly help would-be defendants anticipate and prioritize compliance obligations."). To meet this standard, a relator may turn to several kinds of evidence: "Proof of materiality may include an express, material condition of payment [within the relevant regulations or statutes], or knowledge by the defendant that the government routinely refuses to pay claims based on failure to comply with a certain requirement," regardless of whether that requirement is an express prerequisite to payment. *Camelot Counseling*, 2016 WL 5416494 at *8 (applying *Escobar*). Whether a regulatory "provision is labeled a condition of payment" on its face "is relevant to but not dispositive of the materiality inquiry." *Escobar*, 136 S. Ct. at 2001. The Amended Complaint alleges none of these things whatsoever, falling well short of the "rigorous" materiality requirement under the FCA. *Escobar*, 136 S. Ct. at 2002.

Specifically, Lacey does not allege facts showing that the government routinely refuses to pay claims based on the failure to provide all services in a Plan of Care—nor can he.[7] Likewise, Lacey does not identify any "express, material condition of payment" requiring VNSNY to provide all services authorized in a Plan of Care to be entitled to payment. While the Amended Complaint cites a variety of regulations that in some way mention Plans of Care, *see* Am. Compl. ¶¶ 31, 50, not one of those regulations states that a provider is entitled to government reimbursement if and only if *all* services contemplated in a Plan of Care are provided. As the Second Circuit has cautioned, the FCA is not—and ought not become—a "blunt instrument" of quasi-regulatory enforcement, wielded at will by private relators to enforce regulations that do not pertain to payment conditions. *Mikes*, 274 F.3d at 700; *Escobar*, 136 S. Ct. at 2003 ("The [FCA] is not an all-purpose antifraud statute . . . or a vehicle for punishing garden-variety breaches of contract or regulatory violations" (internal quotation marks and citations omitted)).

It is true enough that, to qualify for Medicare coverage and "[a]s a condition for payment," a physician must certify (among other things) that a "plan for furnishing the services has been established and will be or was periodically reviewed by a physician." 42 C.F.R. §§ 424.22 (a)(1)(i), (iii) (emphasis added). Here, however, there is no allegation whatsoever that Plans of Care were not "established" as required by Section 424.22. Nor is the physician's certification of particular services contained in Plans of Care an unchangeable edict. As the

[7] The Amended Complaint asserts that CMS "routinely terminates from the Medicare program" providers "that fail to follow their patient Plans of Care by providing fewer visits than those ordered by the referring physicians." Am. Compl. ¶ 55. As support, Lacey cites a number of HHS Departmental Appeals Board ("DAB") decisions upholding terminations. Am. Compl. ¶¶ 55-57. This misses the mark. Those inapposite decisions pertain to termination of providers who failed to comply with numerous Medicare conditions of participation, where such failures resulted in documented, repeated, and serious patient harm. *See, e.g.*, *Nightingale Home Healthcare, Inc. v. Ctrs. for Medicare & Medicaid Servs.*, No. C-16-254, 2016 HHSDAB LEXIS 93, *2, *6 (HHS DAB May 9, 2016) (noting that petitioner "failed to comply with more than one condition of participation" placing "patients in immediate jeopardy" that "was particularly egregious in that it harmed patients"). None of the cited DAB decisions addresses the government's decision to reimburse particular claims; whether the providers owed money back to Medicare with respect to any such claims; or indeed any conditions of payment whatsoever. Moreover, the egregious patterns of documented patient harm addressed in those decisions are simply not alleged in the Amended Complaint; nor could they be, since they do not exist here.

United States recognized in a statement of interest submitted in another non-intervened FCA action in the Middle District of Tennessee—and as the Court of Appeals for the Sixth Circuit later agreed on appeal—a physician's certification upon referral to a home health agency, including as to the presence of a Plan of Care for the patient, is a "forward-looking projection of medical need" and "not a backward-looking analysis of the medical necessity of services performed by a home health agency during a sixty-day episode." U.S. Statement of Interest, *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, No. 3:12-cv-00764 (M.D. Tenn. Feb. 24, 2015), ECF Dkt. 66, at 3; *see also Prather*, 838 F.3d. 750, 762 (6th Cir. 2016) (adopting same phrasing from U.S. Statement of Interest). Simply put, the Amended Complaint's repeated contentions concerning alleged deviations from Plans of Care do not support an inference that any precondition to payment was violated.

b. Lacey's Allegations of Falsified Home Visit Verification Data Fail as a Matter of Law

The Amended Complaint's second theory is that VNSNY nurses and therapists failed to "verify each home health care visit they [made] by obtaining the patient's electronic signature (on a tablet computer) and calling from the patient's [home] phone into" a VNSNY contemporaneous verification system, Am. Compl. ¶ 64, and that this failure somehow resulted in the submission of false claims. Here, Lacey's theory is wholly divorced from Medicare's governing rules and regulations, driven yet again by a fundamentally incorrect suggestion that home health services are reimbursed on a fee-for-service basis. They are not, and Lacey's theory consequently fails. Moreover, the visit verification requirements to which Lacey points are what "VNSNY requires"; they are confirmatory safeguards that VNSNY instituted solely on its own initiative, not statutory or regulatory requirements. *Id.* Thus, even if Lacey's factual allegations concerning the home visit verification data were plausible on their face—and they are not—

Lacey's contentions would amount only to a claim that VNSNY failed to adhere to electronic verification systems that the agency voluntarily adopted. Lacey raises no allegation that VNSNY failed to comply with any legal requirement, and has not pled facts showing fraud on any government program.

A violation of internal company policy does not trigger FCA liability. *See, e.g.*, *United States ex rel. Howard v. Lockheed Martin Corp.*, 14 F. Supp. 3d 982, 1007 (S.D. Ohio 2014) (finding for defendant where relators "identified only an internal operations procedure alleged to have been violated"); *United States ex rel. Jallali v. Sun Healthcare Grp.*, No. 12-61011-CIV, 2015 WL 10687577, at *2 (S.D. Fla. Sept. 17, 2015) (dismissing a complaint where relator "appear[ed] to conflate the internal processes of maintaining patient records with the separate act of billing the government"). Instead, to state an FCA claim, Lacey must plausibly allege that VNSNY failed to comply with a requirement—*imposed by the government* and relevant to the "government's disbursement decision[]"—with which VNSNY had to comply in order to receive payment. *Mikes*, 274 F.3d at 697, 699 (implied false certification is based on premise that submitting a claim "implies compliance with governing federal rules that are a precondition to payment"); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010) ("unless *the Government* conditions payment on a certification of compliance, a contractor's mere request for payment does not fairly imply such certification." (emphasis added)). The Amended Complaint does not make such an allegation.[8]

[8] Indeed, New York's Medicaid program expressly excepts skilled nursing visits from "electronic visit verification" requirements that pertain to home health aides. *See* Office of the Medicaid Inspector General, New York State Medical Assistance Requirements – Home Health Providers and Verification Organizations, at 6 (noting that "HHA [Home Health Aide] and PCA [Personal Care Aide] are the only required verifiable services"), https://omig.ny.gov/newsite/images/stories/HomeHealth/nysmedicaidrequirementsforhomehealthprovidersandverificationorganizations5-21-15.pdf). To be clear, the Amended Complaint does not allege that VNSNY failed to adhere to New York's visit verification requirements applicable to home health aides.

Lacey's only available argument is therefore that VNSNY somehow submitted claims for payment to the government that were factually false by virtue of the alleged failure of individual clinicians to comply with internal verifications measures in all instances. Lacey alleges that internal audit reports show examples where VNSNY nurses were unable to obtain patient signatures and/or unable to confirm visits from patients' home telephones. Am. Compl. ¶¶ 70, 72. Lacey also alleges that certain nurse visit reports reflect an unusually high frequency and short duration for nursing visits. Am. Compl. ¶¶ 67-69. From these records, Lacey draws the astoundingly sweeping inference that "[f]or each of these visits – and for tens of thousands of additional visits – VNSNY has billed and received payment from Medicare and Medicaid even though it has known or should have known that all these visits did not occur or did not last long enough for VNSNY to provide any kind of meaningful care, let alone the critical care ordered in the patient Plans of Care." Am. Compl. ¶ 71 (emphasis added).

Lacey's inference is not warranted by the facts alleged. To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), Lacey must allege facts that, if true, "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678. As the Second Circuit has emphasized, "plausibility depends on a host of considerations," including "the existence of alternative explanations so obvious that they render [the] plaintiff's inferences unreasonable." *Pantoja v. Banco Popular*, 545 F. App'x 47, 49 (2d Cir. 2013) (internal citations omitted) (affirming dismissal of complaint for lack of plausibility). Here, the only factual basis Lacey alleges to support his assertion that VNSNY billed the government for home visits that did not occur lies in the verification data for home visits that Lacey insists were too numerous or rapid to be accurate. Am. Compl. ¶¶ 67, 69. On their face, those data trends do not demonstrate the systematic errors that Lacey asserts or that the underlying home visits were fictitious.

A high volume of patient visits, like many visits in a single day, signifies nothing on its own—and the Amended Complaint offers nothing more. New York City, where VNSNY operates, contains some of the most densely populated neighborhoods in the country, and home health therapists and nurses care not only for patients living in clustered apartments in the same buildings but also for those dwelling even closer together in institutional and congregate care settings. *See, e.g.*, Am. Compl. ¶ 70 (referencing nurse visits "at an 8-story congregate care facility"). Furthermore, some skilled nursing visits are routine and quickly completed (*e.g.*, for the purpose of administering injections to an insulin-dependent diabetic); neither Medicare nor Medicaid imposes a minimum time requirement for a skilled visit. In light of these obvious alternative explanations for a high volume of (or short duration for) nurse visits, Lacey's hyperbolic allegations are wholly untethered to any plausible state of facts and are therefore insufficient to state a claim. *Pantoja*, 545 F. App'x at 49.

To the extent that the patterns Lacey discerns could be read to suggest anomalies in documentation, such errors standing alone would be at least as indicative (if not more so) of sloppy or lax record-keeping as of any nefarious intention to make up visits that did not occur.[9] For example, Lacey singles out a nurse in Queens who "claimed to have made 7 patient visits in 42 minutes" on a single day, with similarly short periods reported for visits on other days. Am. Compl. ¶ 70. Missing from the Amended Complaint, however, is any allegation that such data trends were not simply the result of a clinician entering the visits into VNSNY's system at inaccurate times, such as would occur if the clinician completed documentation on several patients in a row after all visits were completed. In other words, Lacey's factual allegations at

[9] Allegations that "as likely evince[] negligence as [they do] actual knowledge, deliberate ignorance, or recklessness" do not state an FCA violation. *United States ex rel. Stone v. Omnicare, Inc.*, No. 09-C-4319, 2012 WL 5877544, at *1 (N.D. Ill. Nov. 20, 2012) (dismissing FCA complaint); *see also Mikes*, 274 F.3d at 703 (noting that "negligence or innocent mistake" is insufficient under the FCA).

most suggest that the home visit verification data are inaccurate in some respect, but that alone provides no factual basis for leaping to the conclusion that home visits were fabricated. *Camelot Counseling*, 2016 WL 5416494, at * 4 (granting in part motion to dismiss concerning allegations of behaviors "that reflect an inattention to detail, accompanied by conclusory labels describing the conduct as fraudulent"). Lacey alleges no facts to bridge the gap between the purportedly inaccurate verification data and what in fact occurred during any nurse or therapist visits.

Yet Lacey does not stop there: the Amended Complaint asks the Court to draw yet further unwarranted and impermissible inferences. There is no allegation—and certainly no allegation with the specificity required by Fed R. Civ. P. 9(b)—that the home visit data have any nexus to any false claim that did not satisfy all material legal requirements, beyond Lacey's staggeringly broad assertion that "for tens of thousands" of visits, VNSNY billed and received payment from the government for visits that did not occur or were unusually brief. Lacey fails to allege—because he cannot—that the duration of any visit rendered any services ineligible for reimbursement and any resulting claim for payment "false." And even if certain therapy visits reflected in the data were actually fabricated, the Amended Complaint does not allege that such extra visits, when accounted for in the final Medicare claim, had any impact on the acuity-based reimbursement tier payable for that episode under Medicare's prospective payment methodology. *See supra*, pages 3-4. Lacey's allegations fare even worse with respect to nursing visits, since the number of nursing visits does not drive the applicable HHRG for the Episode of Care. *See supra*, note 2. Much as Lacey might wish to suggest otherwise, Medicare reimbursement for home health agency services is no longer determined on a fee-for-service basis, and application of Medicare's per-episode reimbursement rules strips Lacey's allegations of any force. *See Bishop*, 823 F.3d at 39 (FCA complaint must "plausibly connect[]" the defendant's alleged conduct to "claims submitted to the government for payment").

In short, while Lacey may have identified instances in which VNSNY employees perhaps failed to adhere to internal policy, the Amended Complaint does not allege facts that, if true, demonstrate an FCA violation.

c. Lacey's Miscellaneous Allegations of Improper Medicare and Medicaid Billing, Including for Dual-Eligible Patients, Fail As a Matter of Law

In a final effort to craft a False Claims Act theory, the Amended Complaint includes a scattershot collection of allegations that VNSNY submitted false claims by virtue of its failure to comply with the rules that control billing for home health aide tasks such as housekeeping services and billing for aide visits to beneficiaries of both Medicare and Medicaid, as well as aide supervision requirements. A closer examination of the governing statutes and regulations reveals that none of the facts alleged, even if true, would be a basis for FCA liability.

i. Billing for Custodial Care

The Amended Complaint alleges that VNSNY submitted false claims by improperly billing the Medicare program for non-covered "custodial care" services VNSNY provided (such as cleaning, cooking, and laundry) as if those services were covered "personal care" services (such as bathing and grooming). Am. Compl. ¶ 75. Lacey alleges that VNSNY sometimes "re-coded" custodial care tasks so that they would appear as personal care tasks on Medicare bills, though Lacey also perplexingly states that VNSNY sometimes billed, and was paid for, "custodial care services it does not re-code." Am. Compl. ¶ 76.

These allegations do not state a claim under the FCA. To the extent that Lacey is suggesting a bright-line rule that custodial care services are non-reimbursable under Medicare, he is flatly wrong. Medicare regulations make clear that home health aides may provide not only "personal care" services but also custodial care services of the kind Lacey describes so long as they are "incidental to a visit that was for the provision of [covered] care. . . . For example, these incidental services may include changing bed linens, personal laundry, or preparing a light meal." 42 C.F.R. § 409.45(b)(4). In any event, as discussed above, payment for home health care is not fee-for-service; the episodic payment is reimbursement for all home health services provided in that period. 42 C.F.R. § 484.205(b) (episodic payment "represents payment in full for all costs associated with furnishing home health services"). VNSNY would therefore not benefit by billing Medicare for additional custodial care services; Medicare's payment is set by the HHRG score for the entire Episode of Care, regardless of the specific number of home health aide visits that occur. Simply put, the facts Lacey alleges, even if true, would not result in a false claim to the Medicare program.

ii. Billing for Dual-Eligible Beneficiaries

The same deficiency plagues Lacey's allegations that VNSNY billed too many hours of home health aide time to Medicaid for patients dually eligible for Medicare and Medicaid benefits. Am. Compl. ¶¶ 82-88. The Amended Complaint includes tables purporting to set out the "disproportionate" allocation of hours between VNSNY's Medicare and Medicaid bills, Am. Compl. ¶ 85, but this allegation amounts to nothing. Because reimbursement is made on a flat, episodic basis and not premised on a fee-for-service or per-hour methodology, *see supra*, pages 3-4, Lacey's factual allegations do not support a contention that VNSNY submitted any false claim to the government.

iii. Home Health Aide Supervision

Finally, Lacey contends that VNSNY submitted false claims because it did not comply with rules requiring regular nurse or therapist supervision of home health aides in the field. Am.

Compl. ¶ 89. Medicare regulations *do* include such requirements, but they are not a prerequisite to payment. *See* 42 C.F.R. § 484.36(d). The Amended Complaint does not contend otherwise. Rather, Lacey asserts that *Medicaid* treats such supervision requirements "as a strict condition of payment," Am. Compl. ¶ 90, in apparent reliance on 18 N.Y.C.R.R. § 505.23(a)(2)(iii) & (b)(1). *See* Am. Compl. ¶ 89. Lacey's theory of FCA liability is left unexplained, but to the extent the Amended Complaint attempts to make out a claim of implied false certification with respect to this purported requirement, Lacey would be required to plead "specific representations" to the government about the services provided, as well as VNSNY's "failure to disclose noncompliance" with material payment conditions. *Escobar*, 136 S. Ct. at 2001. The Amended Complaint meets neither requirement. Instead, the Amended Complaint refers to a 2013 internal VNSNY report (which is not attached) identifying "roughly 100,000 instances where VNSNY failed to provide this required supervision." *Id.* But Lacey does not allege that a single one of those instances involved a patient whose care was reimbursed by Medicaid, much less any "specific representations" made in connection with purported instances of noncompliance with Medicaid's rules. Lacey has not alleged facts supporting any legally cognizable FCA claim.

II. RELATOR'S FRAUD CLAIMS DO NOT MEET THE PARTICULARITY REQUIREMENTS OF RULE 9(B)

a. Heightened Pleading Requirements Apply to FCA Claims

Even if Lacey's claims were founded on sound legal theories, the Amended Complaint must still be dismissed in its entirety for failure to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). It is "self-evident that the FCA is an anti-fraud statute" and that therefore "claims brought under the FCA fall within the express scope of Rule 9(b)." *Wood ex rel. United States v. Applied Research Assocs., Inc.*, 328 F. App'x 744, 747 (2d Cir. 2009). Pleadings subject to Rule 9(b) must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 25 (2d Cir. 2016). "Fraud is a serious allegation, and Rule 9(b) provides meaningful protection against blunderbuss claims of fraud." *Scharff*, 2016 WL 5416494, at *7.

Thus, in an FCA action, "Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how" of the fraudulent conduct by which a defendant knowingly submitted false claims. *Ping Chen ex rel. United States v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 301 (S.D.N.Y. 2013). In addition, the claim of fraud must be "linked to allegations, stated with particularity, of actual false claims submitted to the government." *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 510 (S.D.N.Y. 2014) (noting the widespread adoption within the Second Circuit of the Rule 9(b) standard announced by the First Circuit in *United States ex rel. Karvelas v. Melrose–Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir.2004)); *Ping Chen*, 966 F. Supp. 2d at 301 (a plaintiff "must not only allege with particularity the 'underlying schemes and other wrongful activities' but also the resulting 'submission of fraudulent claims'").[10] The Amended Complaint fails to meet this burden, and Lacey's claims must therefore be dismissed.

b. The Amended Complaint Fails to Plead Actual False Claims With Particularity

It is well-settled law that "a plaintiff cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted. [A relator] must also plead the 'claim' submission element with particularity." *United States ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 253 (S.D.N.Y. 2014). "Standing alone, allegations of violations of federal regulations are insufficient" to satisfy Rule 9(b). *United States ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 5:09-CV-00710, 2011 WL 167246, at *10 (N.D.N.Y. Jan. 19, 2011).

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[10] Where, as here, the relator is a corporate insider of the Defendant, no relaxation of Rule 9(b)'s requirements is appropriate. *See, e.g., United States v. Lab. Corp. of Am. Holdings*, No. 107CV05696ALCRLE, 2015 WL 7292774, at *4 (S.D.N.Y. Nov. 17, 2015).

Courts within the Second Circuit have made clear what types of information may satisfy this requirement in a FCA action:

> [D]etails concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a [plaintiff] to state his or her claims with particularity.

Bilotta, 50 F. Supp. 3d at 510. Although such "details do not constitute a checklist of mandatory requirements . . . some[] of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b)." *Id.* All of Lacey's theories fail to meet this standard.

First, with respect to Lacey's home visit verification allegations, the Amended Complaint fails to plead fraud with particularity because it identifies no nexus between the internal VNSNY records Lacey describes and the submission of any claims for payment whatsoever. FCA pleadings "invariably are inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action." *United States ex rel. Mooney v. Americare, Inc.*, No. 06-CV-1806 FB VVP, 2013 WL 1346022, at *3 (E.D.N.Y. Apr. 3, 2013). The Amended Complaint tries to distract from this failing by listing "several patient and nurse-specific examples of VNSNY nurses" who allegedly failed to obtain patient verification signatures, Am. Compl. ¶ 70, or reported visits "within a window too narrow to deliver any services," *id.* at ¶ 69, or reported a high volume of patient visits, *id.* at ¶ 68. But Lacey fails to allege with particularity how data relating to those trends factored into any VNSNY claims to Medicare or Medicaid, or how (if at all) those trends influenced any claim for payment within Medicare's acuity-adjusted episodic payment tiers. Instead, Lacey asserts the sweeping conclusion that for "each of these visits – and for tens of thousands of additional visits" VNSNY billed for and received payment from the government when it was entitled to nothing. Am. Compl. ¶ 71. No attempt is made to substantiate that broad allegation with even a scintilla of detail as to specific claims for payment to any government health care program. Dismissal is required on that basis alone. *Ping Chen*, 966 F. Supp. 2d at 302 ("[n]o amounts of charges were identified. No actual dates were alleged. . . . No copy of a single bill or payment was provided." (citing *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1312 (11th Cir. 2002))).

Second, Lacey does not allege with particularity any details that, if true, would show that the alleged failure to obtain patient signatures or telephone call confirmation was anything other than sloppy adherence to internal verification requirements. That is, the Amended Complaint "does not allege with particularity how this conduct rises to the level of fraud." *Scharff*, 2016 WL 5416494, at *4. The Court's decision in *Scharff* is instructive. There, the relator alleged that a counselor working for a New York City-based outpatient counseling and educational services provider "failed to obtain approximately 450 required patient signatures for her treatment plans, and that another counselor failed to obtain signatures in approximately sixty instances." *Id.* at 5. In holding that the complaint did not plead fraud with particularity, the Court noted that the relator "fails to allege with particularity why these practices were fraudulent, as opposed to sloppy, and does not identify their consequences for [the defendant's] Medicaid reimbursement claims." *Id.*; *see also id.* at *8 (noting the complaint did "not attach a sample of any false claim or describe the contents or format of [defendant's] reimbursement claims," and it was "unclear whether [defendant] made any certification as to its practices for collecting patient signatures and whether forms signed by patients were submitted as part of Medicaid reimbursement claims"). The same principles apply fully to Lacey's allegations concerning nurse and therapist visit verification data, requiring dismissal of those claims.

Lacey's failure to identify any actual false claims with particularity is even more glaring with respect to the Amended Complaint's miscellaneous allegations concerning custodial tasks, dual-eligible beneficiaries, and inadequate nurse supervision. *See* Am. Compl. ¶¶ 75-91. Here, Lacey does not even attempt to identify particular claims for payment. Instead, the closest the Amended Complaint comes are the vague allegations in paragraphs 77-78 as to patients purportedly listed on two reports (which are not attached to the Amended Complaint) for whom VNSNY billed Medicare for "hours of custodial care services." As discussed above, Medicare does not reimburse providers of home health services on a per-hour, per-visit, or other fee-for-service basis, but instead provides reimbursement for an Episode of Care. Because Lacey provides no details as to any particular Medicare claim with respect to these allegations, Lacey simply has not alleged whether—or how—these hours of "custodial care services" had any impact on any claim VNSNY submitted to the Medicare program. Precisely the same fault dooms Lacey's allegations concerning missed supervision visits. *See* Am. Compl. ¶ 90. Finally, there is not one example of a particular Medicare or Medicaid claim identified with respect to Lacey's dual-eligible theory. Instead, the Amended Complaint presents aggregated data covering a six year period, Am. Compl. ¶ 85, paired with a conclusory statement that VNSNY should have billed "a much higher percentage of" its total hours to Medicare as compared to Medicaid. Am. Compl. ¶ 86. Not even one example of a particular false claim is identified.[11]

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[11] Nor do Lacey's blanket allegations that VNSNY "submitted claims" in connection with all of these alleged practices pass muster under Rule 9(b). "[A] complaint's description of a fraudulent scheme paired with information about a defendant's standard billing practice is not enough 'particular' information to fulfill the purposes of Rule 9(b)." *Scharff*, 2016 WL 5416494, at *7.

Lastly, with respect to Lacey's Plan of Care allegations, the Amended Complaint again fails to allege any actual bills or claims to a government health care program; who submitted such claims; when they were submitted; or, for many of the examples in the Amended Complaint, what amount VNSNY allegedly billed or the government allegedly paid. This pleading failure is grounds for dismissal. *Wood*, 328 Fed. App'x at 750 (describing allegations as "plainly insufficient" under Rule 9(b) where plaintiffs failed to "cite to a single identifiable record or billing submission they claim to be false, or give a single example of when a purportedly false claim was presented for payment by a particular defendant at a specific time"). Lacey's allegations fall well short of the types of details that courts within the Second Circuit have held to be sufficient. *See, e.g.*, *N. Adult Daily Health Care Ctr.*, 2016 WL 4703653, at *7 (finding that complaint satisfied Rule 9(b) where relator "provide[d] sixteen specific examples of false claims with annexed billing details," including "a location code, category code, registrant identification code, the amount paid, a service code, a daily rate and dates of service").

Although Lacey identifies specific dollar amounts that VNSNY allegedly billed and received from the government in connection with certain of his Plan of Care allegations, *see* Am. Compl. ¶ 44, this is insufficient under Rule 9(b).[12] Lacey fails to allege whether those amounts were more than, less than, or the same as would have been submitted to the government had all the care contemplated in the Plans of Care been provided. As discussed above, Medicare's regulations describe various mechanisms for addressing any relevant deviations from the services forecasted in a Plan of Care at the outset of an episode.[13] *See, e.g.*, Medicare Manual, §

[12] For certain other examples, Lacey asserts that patients received none of the services set out in their Plan of Care. Am. Compl. ¶ 45. Conspicuously absent from these examples is any allegation of when or in what amount any government health care program was billed, or what amount was ever paid.

[13] There are many reasons why a patient might receive fewer home care services than originally anticipated in a Plan of Care (*e.g.*, early patient recovery; patient refusals of care; change in geographic location; receipt of therapy at an

10.1.19.1. Nowhere does the Amended Complaint allege with any particularity that VNSNY failed to adhere to these procedures. Nor does the Amended Complaint allege with any particularity how—or even *if*—the alleged deviations from Plans of Care for identified patients would have affected the HHRG classification assigned to, and used to determine the ultimate reconciled payment for, a given Episode of Care. Simply put, there are no facts alleged showing that any deviation from even one Plan of Care caused the government to be fraudulently billed or over-billed for any home health services.

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The Amended Complaint does not identify a single false claim for payment submitted to Medicare or Medicaid. Nor does Lacey identify anyone who submitted any false claims, the particular dates on which such submissions occurred, or any details about the content of any claims forms. The Amended Complaint falls well short of pleading fraud on the government with particularity. *Bilotta*, 50 F. Supp. 3d at 510; *United States v. LifePath Hospice, Inc.*, No. 8:10-CV-1061-T-30TW, 2016 WL 5239863, at *7 (M.D. Fla. Sept. 22, 2016) (dismissing complaint with prejudice where relator "describe[d] a private scheme in detail, to include facts as to some disturbing medical practices" but not "time, place, and substance of the defendant's alleged fraud"). Having failed to satisfy Rule 9(b)'s requirements, the Amended Complaint should be dismissed in its entirety.

III. THE AMENDED COMPLAINT MUST BE DISMISSED INSOFAR AS IT ALLEGES CONDUCT OUTSIDE THE STATUTES OF LIMITATIONS

Lacey alleges that VNSNY's relevant conduct "has occurred since at least 2004." Am. Compl. ¶ 92. However, any allegations as to false claims submitted prior to July 28, 2008—that is, six years prior to the filing date of the original complaint—are barred by the federal FCA's

outpatient site; retention of a private nurse; untimely death). In such circumstances, and in many others, it would be entirely appropriate for a patient to receive fewer services than originally forecasted in a Plan of Care.

statute of limitations. *See* 31 U.S.C. § 3731(b)(1); *United States v. Rivera*, 55 F.3d 703, 707 (1st Cir. 1995) (FCA statute of limitations runs from when claim for payment is submitted). Although the New York FCA has a longer ten-year limitations period, N.Y. Fin. Law. Art. 9, § 192, only allegations as to false claims submitted to New York's Medicaid program can survive beyond the federal FCA's six-year limitations period. In other words, claims as to Medicare outside the six-year period are time-barred.

IV. THE AMENDED COMPLAINT SHOULD BE DISMISSED WITH PREJUDICE

Lacey initiated this action in July 2014, and filed the First Amended Complaint two years later, on July 28, 2016. *See* ECF Dkt. 15 (unsealing previously filed complaints). Lacey has had ample opportunity since July 2014 to state a viable cause of action but has simply failed to do so. Further opportunities to revise his allegations would waste the parties' and Court's resources. Accordingly, the Court should dismiss this action with prejudice. *See Pasternak v. Lab. Corp. of Am.*, 892 F. Supp. 2d 540, 548-49 (S.D.N.Y. 2012).

CONCLUSION

For the foregoing reasons, VNSNY respectfully requests that the Court dismiss the Amended Complaint with prejudice.

Dated: November 21, 2016

Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that on November 21, 2016, I caused a true and correct copy of the foregoing document to be served upon all counsel of record via the CM/ECF system. I also certify that a true and correct copy of the foregoing is being served by U.S. Mail upon the following:

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